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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/697,546
Filing Date: October 30, 2003
Appellant(s): WYNN ET AL.

William E. McGowan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/22/10 appealing from the Office action mailed 9/10/09.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Currently claims 13-16, 18-22, 26-27, 29-31, 36-42 and 47-52.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN

REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

4,828,840	SAKAMOTO et al	5-1989
6,126,969	SHAH et al	10-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13-16, 18-22, 26, 27, 29-31, 36-42 and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Shah et al (USPN 6,126,969 hereafter '969) in view of Sakamoto et al (USPN 4,828,840 hereafter '840). The claims are drawn to a dosage form comprising an immediate release and sustained release portion, where the dosage from has a liquid vehicle forming a liquid suspension.

The '969 patent teaches a dosage form comprising an immediate release portion comprising uncoated drug particles, and an extended releasing portion, comprising coated drug particles (abstract). The dosage from comprises sweeteners and other excipients (col. 7, lin. 15-30). The extended release portion comprises coated core particles where the coating comprises water insoluble polymers such as ethylcellulose and cellulose acetate (col. 4, lin. 63-65, example). The coating comprises a combination of multiple polymers types and copolymers including film-forming polymers (col. 4, lin. 40-58). The active agents include various well-known drugs including ibuprofen and other NSAID such as naproxen (col. 6, lin. 14-15). Another embodiment of the invention has the coated particles in a concentration of approximately 20.79% (table 1). The formulation comprises polyethylene glycol (Table 1 and 2). Regarding the therapeutic effect of the dosage form, it is the position of the Examiner that such limitations are inherent features of the composition. Regarding the liquid suspension limitation, the '969 patent is suggestive that the formulation (a combination of coated and uncoated particles providing a combination immediate and sustained release delivery) can be dispersed in water in order to form a suspension (col. 4, lin. 15-17). The reference is however, not explicit about the exact structure of the liquid suspension; it is the position of the Examiner that the concentrations would be similar to those of the controlled release formulation. It is the position of the Examiner that these concentrations represent an optimization of ranges and are not inventive barring a showing of unexpected results.

The reference is silent to the ratio of the water insoluble polymer relative to the enteric polymers recited in the instant claims. This ratio is well within the level of skill in the art as seen in the '840 patent. The '840 patent discloses a controlled releases formulation comprising a

coated dosage from where the coating comprises a combination of water-insoluble polymers and enteric polymers (abstract). The formulation can last for longer than 10 hours (col. 2, lin. 30-35) and can comprise a wide range of active agents. The film coating comprises water-insoluble polymers such as cellulose acetate, ethylcellulose and copolymers of polymethacrylate and trimethylammoniumethyl chloride methacrylate sold as Eudragit RS (col. 4, lin. 5-15). The enteric polymers include hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose succinate acetate and copolymers of methacrylic acid and polymethyl methacrylate (col. 4, lin. 16-25). The water-insoluble polymers are combined with the enteric polymers to form an extended release coating where the insoluble polymer is present in a ratio to the enteric polymer of 8.7:1 (example 13) within the limits of the instant claims.

Regarding the specific ratios and ranges of the instant claims, it remains the position of the Examiner that the prior art combination would obviate these limitations. The general conditions of the claims have been met by the combined prior art, namely a liquid suspension of particles comprising a portion of uncoated and a portion of coated particles is suspended in water. The coated particles comprise a combination of water insoluble and enteric polymers present in a ratio within the range of the instant claims. Applicant is reminded that when the general where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time

of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Regarding the pKa of the at least one active agent contained in the sustained release particles and its relation to the pH of the suspension it is the position of the Examiner that the prior art inherently meets this limitation. It is the position of the Examiner that the pKa is a function of the structure of the instant invention, and is due to the arrangement of the immediate and sustained release particles. Since the prior art discloses the same arrangement of particles and components, the prior art must also possess the same pKa and pH limitations as the instant claims. The pKa and its relationship to the pH of the suspension is an inherent feature that cannot be separated from the components of the instant claims. In the instant claims the pKa of the NSAID is higher than the pH of the suspension, the NSAID is more acidic than that surrounding suspension. If ibuprofen (pH of 4.4) is suspended in water (pH of 7) than the claim limitation is met. As such since the prior art discloses a formulation meeting each of the compositional limitations it must also meet the functional limitations inherently.

With these things in mind it would have been obvious to combine the teachings and suggestions of the teachings and suggestions of the prior art in order to provide a stable liquid suspension. It would have been obvious to modify the ratio of polymers in the extended coating of the '969 patent as seen in the '840 patent in order to deliver a stable drug release over an extended period of time, at least 10 hours. It would have been obvious to combine the teachings and suggestions of the prior art with an expected result of a stable controlled release formulation useful in treating pain.

(10) Response to Argument

Applicant argues that:

(1) The '969 patent seeks to avoid the use of enteric polymers all together, alone or in combination with other non-enteric polymers. The 'patent teaches away from the use of enteric polymers and explicitly excludes their use in the combination formulation.

(2) The combination of the prior art, the '969 and '840 does not address how to maintain the pH of the liquid suspension below the pKa of the NSAID, as claimed in the instant claims.

Regarding argument (1), it remains the position of the Examiner that despite the passages recites by applicant the '969 patent continues to suggest the inclusion of enteric polymers in combination with other non-enteric polymers. The passage starting at column 5, line 54, states that the combination formulation is more predictable than conventional enteric sustained release coating compositions. It is the position of the Examiner that this comparison is being made between the combination immediate release/sustained release formulation of the '969 patent and a convention single coating, enteric coating formulation known in the art. The passage is contrasting the combination of an immediate release portion and a controlled release portion with that of a single sustained release portion, and indicating that the combination formulation has a more predictable and reproducible result. There is ***nothing*** in the passage to indicate that enteric polymers should be avoided in the combination formulation. The passage if anything indicates the superiority of the combination formulation of the '969 patent over conventional sustained release preparations (that is only enteric coated formulations of background art, not those of the instant invention in the cited patent). This formulation disclosed by the '969 patent comprises a first portion of uncoated immediate release NSAID particles; a second portion of coated particles

comprising the same NSAID, wherein the coating can comprise multiple polymers (col. 4, lin. 43-46), including enteric polymers such as cellulose acetate phthalate (col. 4, lin. 65), identified in instant claim 14 as enteric, and ethylcellulose (col. 4, lin. 63), identified in instant claim 13 as an insoluble film forming polymer. Clearly, the '969 patent teaches combinations of polymers and recites some of the same polymers defined by the instant specification as being enteric and insoluble film forming polymers. As such the '969 patent in the passage starting at column 5, line 54 indicates the superiority of a formulation comprising multiple polymers including enteric polymers (note as stated above, some of the polymers listed in column 4, (cellulose acetate phthalate) is an enteric polymer as defined by appellent own specification. Further, many of the other polymers listed are within the scope of being an "enteric polymer" since they are water insoluble, e.g., various methacrylic polymers, etc.. The combination immediate release and sustained release formulation can be packaged into a pouch and dispersed in water to form a suspension (col. 4, lin. 15-18). The '969 patent discloses an identical formulation comprising the same uncoated NSAID particles, coated NSAID particles with a combination of water-insoluble film forming polymers and enteric polymers recited in the instant claims. This combination embodiment is preferred over conventional single release sustained release formulations and is identical to that of the instant claims. For these reasons the claims remain obviated.

Regarding argument (2), it remains the position of the Examiner that the recited pKa limitation is an inherent functional limitation of the NSAID and not a feature as recited in the Appeal Brief. The pKa is a measure of the acidity of a compound in solution, but as the claim is written the pKa is a feature of the NSAID, and not as argued by Applicant a measure to maintain the pH of the suspension. Nothing in the claims indicates that a particular the pH must be

maintained through a method step or action. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., maintenance of the pH of a liquid suspension below the pKa of an NSAID) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As such, the claims are written in product form, where the pKa limitation appears as a functional limitation inherent to the NSAD, and since a compound and its properties cannot be separated the same NSAID of the instant claims would have the same pKa property. The '969 patent provides combination formulation comprising the same disposition of drug particles, both coated and uncoated suspended in water, where the NSAID particles can be ibuprofen (col. 6, lin. 14-15) as required by the instant claims. Whether or not the pH is maintained is irrelevant since the product claims do not require pH maintenance. Further according to the instant Specification the only way to achieve the argued pH maintenance is through the use of specific concentrations of buffering agents (page 11, lines 35-38). Neither these buffer agents, nor their specific effective amount are recited in the instant claims. As such there would be no way for the pH to be maintained in relation to the pKa of the NSAID unless it was an inherent property of the drug and not a function of method step as argued by applicant. For these reasons, it remains the position of the Examiner that the pKa limitation is merely an inherent feature of the compound, which can be ibuprofen. The '969 patent discloses a combination formulation comprising uncoated immediate release ibuprofen particles and sustained release ibuprofen particles suspended in water to form a suspension. For these reasons the claims remain obviated.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

Conferees:

/MICAH-PAUL YOUNG/

Examiner, Art Unit 1618

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612